TABLE 14.2.1-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker: HDL-Cholesterol (mg/dL)

Timepoint	Statistic	Smokers	Non-Smokers	P-value[c]
Week 1	N	50	66	0.0012
	MEAN, GEO MEAN	47, 45	55, 53	
	SD, SE	11.7, 1.7	14.9, 1.8	
	MEDIAN	48	53	
	MIN, MAX	23, 81	26, 96	
	5%, 95%	30, 62	34, 79	
	BLQ Values Included	0	0	
Week 3	N	46	66	0.0003
	MEAN, GEO MEAN	46, 44	54, 52	
	SD, SE	12.8, 1.9	13.7, 1.7	
	MEDIAN	44	52	
	MIN, MAX	24, 79	31, 86	
	5%, 95%	28, 66	33, 81	
	BLQ Values Included	0	0	
Week 6	N	42	66	0.0002
	MEAN, GEO MEAN	45, 43	54, 52	
	SD, SE	11.0, 1.7	13.0, 1.6	
	MEDIAN	45	54	
	MIN, MAX	28, 82	29, 89	
	5%, 95%	30, 59	37, 78	
	BLQ Values Included	0	0	
Overall[b]	N	50	66	0.0002
	MEAN, GEO MEAN	47, 45	54, 53	
	SD, SE	11.2, 1.6	13.4, 1.6	
	MEDIAN	46	53	
	MIN, MAX	26, 81	29, 85	
	5%, 95%	29, 63	35, 77	

[a] P-value from wilcoxon rank-sum test.
[b] Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

TABLE 14.2.1-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker: HDL-Cholesterol (mmol/L)

Timepoint	Statistic	Smokers	Non-Smokers	P-value[a]
Week 1	N	50	66	0.0012
	MEAN, GEO MEAN	1.21, 1.18	1.42, 1.36	
	SD, SE	0.302, 0.043	0.386, 0.048	
	MEDIAN	1.25	1.36	
	MIN, MAX	0.59, 2.09	0.67, 2.48	
	5%, 95%	0.78, 1.60	0.88, 2.04	
	BLQ Values Included	0	0	
Week 3	N	46	66	0.0003
	MEAN, GEO MEAN	1.19, 1.15	1.40, 1.35	
	SD, SE	0.330, 0.049	0.353, 0.044	
	MEDIAN	1.14	1.33	
	MIN, MAX	0.62, 2.04	0.80, 2.22	
	5%, 95%	0.72, 1.71	0.85, 2.09	
	BLQ Values Included	0	0	
Week 6	N	42	66	0.0002
	MEAN, GEO MEAN	1.15, 1.12	1.39, 1.35	
	SD, SE	0.284, 0.044	0.338, 0.042	
	MEDIAN	1.15	1.40	
	MIN, MAX	0.72, 2.12	0.75, 2.30	
	5%, 95%	0.78, 1.53	0.96, 2.02	
	BLQ Values Included	0	0	
Overall[b]	N	50	66	0.0002
	MEAN, GEO MEAN	1.20, 1.17	1.40, 1.36	
	SD, SE	0.291, 0.041	0.346, 0.043	
	MEDIAN	1.18	1.37	
	MIN, MAX	0.66, 2.08	0.75, 2.21	
	5%, 95%	0.74, 1.64	0.90, 1.99	

[a] P-value from wilcoxon rank-sum test.
[b] Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

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TABLE 14.2.1-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker: LDL-Cholesterol (mg/dL)

Timepoint	Statistic	Smokers	Non-Smokers	P-value[a]
Week 1	N	48	64	0.4837
	MEAN, GEO MEAN	122, 118	113, 109	
	SD, SE	32.3, 4.7	29.8, 3.7	
	MEDIAN	122	110	
	MIN, MAX	55, 231	56, 200	
	5%, 95%	76, 175	75, 173	
	BLQ Values Included	0	0	
Week 3	N	45	66	0.8579
	MEAN, GEO MEAN	115, 112	107, 102	
	SD, SE	26.8, 4.0	30.4, 3.7	
	MEDIAN	116	104	
	MIN, MAX	64, 199	36, 190	
	5%, 95%	69, 154	60, 153	
	BLQ Values Included	0	0	
Week 6	N	42	66	0.8980
	MEAN, GEO MEAN	118, 114	112, 107	
	SD, SE	31.1, 4.8	34.1, 4.2	
	MEDIAN	114	110	
	MIN, MAX	73, 227	29, 214	
	5%, 95%	79, 160	64, 168	
	BLQ Values Included	0	0	
Overall[b]	N	50	66	0.7685
	MEAN, GEO MEAN	119, 116	111, 107	
	SD, SE	28.0, 4.0	28.5, 3.5	
	MEDIAN	119	109	
	MIN, MAX	70, 219	52, 192	
	5%, 95%	76, 167	67, 159	

[a] P-value from wilcoxon rank-sum test.
[b] Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

TABLE 14.2.1-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker: LDL-Cholesterol (mmol/L)

Timepoint	Statistic	Smokers	Non-Smokers	P-value[a]
Week 1	N	48	64	0.4837
	MEAN, GEO MEAN	3.16, 3.05	2.91, 2.81	
	SD, SE	0.835, 0.121	0.769, 0.096	
	MEDIAN	3.16	2.83	
	MIN, MAX	1.42, 5.97	1.45, 5.17	
	5%, 95%	1.97, 4.53	1.94, 4.47	
	BLQ Values Included	0	0	
Week 3	N	45	66	0.8579
	MEAN, GEO MEAN	2.97, 2.89	2.76, 2.65	
	SD, SE	0.693, 0.103	0.786, 0.097	
	MEDIAN	3.00	2.68	
	MIN, MAX	1.66, 5.15	0.93, 4.91	
	5%, 95%	1.78, 3.98	1.55, 3.96	
	BLQ Values Included	0	0	
Week 6	N	42	66	0.8980
	MEAN, GEO MEAN	3.05, 2.96	2.90, 2.76	
	SD, SE	0.803, 0.124	0.882, 0.109	
	MEDIAN	2.95	2.85	
	MIN, MAX	1.89, 5.87	0.75, 5.53	
	5%, 95%	2.04, 4.14	1.66, 4.34	
	BLQ Values Included	0	0	
Overall[b]	N	50	66	0.7707
	MEAN, GEO MEAN	3.08, 3.00	2.86, 2.76	
	SD, SE	0.724, 0.102	0.739, 0.091	
	MEDIAN	3.08	2.82	
	MIN, MAX	1.81, 5.66	1.33, 4.97	
	5%, 95%	1.95, 4.32	1.73, 4.12	

[a] P-value from wilcoxon rank-sum test.
[b] Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

TABLE 14.2.1-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker: Fibrinogen (mg/dL)

Timepoint	Statistic	Smokers	Non-Smokers	P-value[a]
Week 1	N	50	66	0.0000
	MEAN, GEO MEAN	307, 298	255, 245	
	SD, SE	78.7, 11.1	72.4, 8.9	
	MEDIAN	292	254	
	MIN, MAX	186, 573	117, 474	
	5%, 95%	210, 444	153, 383	
	BLQ Values Included	0	0	
Week 3	N	46	66	0.0062
	MEAN, GEO MEAN	300, 285	250, 238	
	SD, SE	103.0, 15.2	78.9, 9.7	
	MEDIAN	300	242	
	MIN, MAX	144, 634	111, 509	
	5%, 95%	155, 483	124, 405	
	BLQ Values Included	0	0	
Week 6	N	42	64	0.0001
	MEAN, GEO MEAN	290, 280	253, 244	
	SD, SE	79.6, 12.3	63.5, 7.9	
	MEDIAN	269	243	
	MIN, MAX	153, 483	123, 394	
	5%, 95%	174, 444	146, 354	
	BLQ Values Included	0	0	
Overall[b]	N	50	66	0.0000
	MEAN, GEO MEAN	301, 294	252, 246	
	SD, SE	71.6, 10.1	57.2, 7.0	
	MEDIAN	292	247	
	MIN, MAX	184, 535	162, 399	
	5%, 95%	203, 444	169, 359	

[a] P-value from wilcoxon rank-sum test.
[b] Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

TABLE 14.2.1-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker: Fibrinogen (g/L)

Timepoint	Statistic	Smokers	Non-Smokers	P-value[a]
Week 1	N	50	66	0.0000
	MEAN, GEO MEAN	3.07, 2.98	2.55, 2.45	
	SD, SE	0.787, 0.111	0.724, 0.089	
	MEDIAN	2.92	2.54	
	MIN, MAX	1.86, 5.73	1.17, 4.74	
	5%, 95%	2.10, 4.44	1.53, 3.83	
	BLQ Values Included	0	0	
Week 3	N	46	66	0.0062
	MEAN, GEO MEAN	3.00, 2.85	2.50, 2.38	
	SD, SE	1.030, 0.152	0.789, 0.097	
	MEDIAN	3.00	2.42	
	MIN, MAX	1.44, 6.34	1.11, 5.09	
	5%, 95%	1.55, 4.83	1.24, 4.05	
	BLQ Values Included	0	0	
Week 6	N	42	64	0.0001
	MEAN, GEO MEAN	2.90, 2.80	2.53, 2.44	
	SD, SE	0.796, 0.123	0.635, 0.079	
	MEDIAN	2.69	2.43	
	MIN, MAX	1.53, 4.83	1.23, 3.94	
	5%, 95%	1.74, 4.44	1.46, 3.54	
	BLQ Values Included	0	0	
Overall[b]	N	50	66	0.0000
	MEAN, GEO MEAN	3.01, 2.94	2.52, 2.46	
	SD, SE	0.716, 0.101	0.572, 0.070	
	MEDIAN	2.92	2.47	
	MIN, MAX	1.84, 5.35	1.62, 3.99	
	5%, 95%	2.03, 4.44	1.69, 3.59	

[a] P-value from wilcoxon rank-sum test.
[b] Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.2.1-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker: C-Reactive Protein (mg/dL)

Timepoint	Statistic	Smokers	Non-Smokers	P-value[a]
Week 1	N	50	66	0.0000
	MEAN, GEO MEAN	0.407, 0.187	0.305, 0.124	
	SD, SE	0.5268, 0.0745	0.7125, 0.0877	
	MEDIAN	0.190	0.121	
	MIN, MAX	0.020, 2.790	0.020, 5.500	
	5%, 95%	0.020, 1.350	0.022, 0.920	
	BLQ Values Included	4	2	
Week 3	N	46	66	0.0001
	MEAN, GEO MEAN	0.408, 0.181	0.219, 0.110	
	SD, SE	0.5164, 0.0761	0.3584, 0.0441	
	MEDIAN	0.236	0.103	
	MIN, MAX	0.020, 1.900	0.020, 2.200	
	5%, 95%	0.020, 1.630	0.027, 0.889	
	BLQ Values Included	5	2	
Week 6	N	42	66	0.0003
	MEAN, GEO MEAN	0.424, 0.195	0.316, 0.123	
	SD, SE	0.5421, 0.0836	0.6368, 0.0784	
	MEDIAN	0.250	0.108	
	MIN, MAX	0.020, 2.480	0.020, 3.560	
	5%, 95%	0.020, 1.500	0.022, 1.590	
	BLQ Values Included	4	2	
Overall[*]	N	50	66	0.0005
	MEAN, GEO MEAN	0.413, 0.211	0.280, 0.135	
	SD, SE	0.4583, 0.0648	0.4363, 0.0537	
	MEDIAN	0.271	0.121	
	MIN, MAX	0.020, 2.300	0.024, 2.267	
	5%, 95%	0.020, 1.277	0.028, 1.093	

[a] P-value from wilcoxon rank-sum test.
[*] Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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TABLE 14.2.1-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker: C-Reactive Protein (mg/L)

Timepoint	Statistic	Smokers	Non-Smokers	P-value[a]
Week 1	N	50	66	0.0000
	MEAN, GEO MEAN	4.07, 1.87	3.05, 1.24	
	SD, SE	5.268, 0.745	7.125, 0.877	
	MEDIAN	1.90	1.21	
	MIN, MAX	0.20, 27.90	0.20, 55.00	
	5%, 95%	0.20, 13.50	0.22, 9.20	
	BLQ Values Included	4	2	
Week 3	N	46	66	0.0001
	MEAN, GEO MEAN	4.08, 1.81	2.19, 1.10	
	SD, SE	5.164, 0.761	3.584, 0.441	
	MEDIAN	2.36	1.03	
	MIN, MAX	0.20, 19.00	0.20, 22.00	
	5%, 95%	0.20, 16.30	0.27, 8.89	
	BLQ Values Included	5	2	
Week 6	N	42	66	0.0003
	MEAN, GEO MEAN	4.24, 1.95	3.16, 1.23	
	SD, SE	5.421, 0.836	6.368, 0.784	
	MEDIAN	2.50	1.08	
	MIN, MAX	0.20, 24.80	0.20, 35.60	
	5%, 95%	0.20, 15.00	0.22, 15.90	
	BLQ Values Included	4	2	
Overall[b]	N	50	66	0.0005
	MEAN, GEO MEAN	4.13, 2.11	2.80, 1.35	
	SD, SE	4.583, 0.648	4.363, 0.537	
	MEDIAN	2.71	1.21	
	MIN, MAX	0.20, 23.00	0.24, 22.67	
	5%, 95%	0.20, 12.77	0.28, 10.93	

[a] P-value from wilcoxon rank-sum test.
[b] Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

TABLE 14.2.1-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker: Malondialdehyde (umol/L)

Timepoint	Statistic	Smokers	Non-Smokers	P-value*
Week 1	N	50	66	0.0435
	MEAN, GEO MEAN	0.51, 0.49	0.45, 0.44	
	SD, SE	0.130, 0.018	0.075, 0.009	
	MEDIAN	0.45	0.40	
	MIN, MAX	0.40, 0.88	0.40, 0.75	
	5%, 95%	0.40, 0.79	0.40, 0.60	
	BLQ Values Included	18	33	
Week 3	N	46	66	0.1653
	MEAN, GEO MEAN	0.54, 0.52	0.46, 0.46	
	SD, SE	0.125, 0.018	0.083, 0.010	
	MEDIAN	0.50	0.43	
	MIN, MAX	0.40, 0.79	0.40, 0.72	
	5%, 95%	0.40, 0.79	0.40, 0.65	
	BLQ Values Included	13	27	
Week 6	N	42	66	0.0000
	MEAN, GEO MEAN	0.43, 0.43	0.51, 0.49	
	SD, SE	0.030, 0.012	0.131, 0.016	
	MEDIAN	0.40	0.44	
	MIN, MAX	0.40, 0.72	0.40, 0.88	
	5%, 95%	0.40, 0.63	0.40, 0.75	
	BLQ Values Included	29	30	
Overall*	N	50	66	0.0000
	MEAN, GEO MEAN	0.50, 0.49	0.47, 0.47	
	SD, SE	0.098, 0.014	0.060, 0.007	
	MEDIAN	0.48	0.47	
	MIN, MAX	0.40, 0.84	0.40, 0.61	
	5%, 95%	0.40, 0.67	0.40, 0.59	

* P-value from wilcoxon rank-sum test.
* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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